



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

HFI-35  
Food and Drug Administration  
Atlanta District Office

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60 8th Street, N.E.  
Atlanta, Georgia 30309

June 15, 2000

**VIA FEDERAL EXPRESS**

William "Eddie" Gordon, President  
Gordon Enterprises, Inc.  
345 Pinckney Street  
McClellanville, SC 29458

**Warning Letter**  
00-ATL-49

Dear Mr. Gordon:

On December 13-15, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant, located at McClellanville, South Carolina. During that inspection, our investigators documented serious deviations from FDA's seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh crabmeat to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations are as follows:

1. You must have a HACCP plan that lists the critical control points, in order to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for fresh crabmeat does not list the cooked crab cooler as a critical control point for controlling the food safety hazard of pathogen growth and toxin formation as a result of time/temperature abuse. This cooler is used to store in-process cooled crabs and claws, which have been previously handled by your employees, and returned for temporary storage before picking at a later time/date. This deficiency was previously brought to your attention during our May 1999 inspection of your facility.
2. You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). However, your HACCP plan for fresh crabmeat lists a critical limit of "4 hours maximum exposure to room temperature" for the picking/boning/packing critical control point (CCP) that is not adequate to control the pathogen growth and toxin formation hazard. Due to room temperature variability, the critical limit as written does not provide the detail needed to control pathogen growth and toxin formation in fresh crabmeat. The critical limit must list the maximum product temperature that can be reached during processing or list an indirect control of the maximum product temperature by listing verified process parameters (i.e. maximum room temperature and time).

3. You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the picking/boning/packing critical control point to control pathogen growth and toxin formation due to temperature abuse as listed in your HACCP plan for fresh crabmeat. Your December 13, 1999 *CRABMEAT TIME RECORD* was not completed for the first two and one half hours of operation. In addition, due to the other incomplete blanks under the "Time When Last Packed" heading on this record, the elapsed time that the crabs and crabmeat are exposed to unrefrigerated conditions can not be determined.
4. You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(b). However, your firm did not adequately monitor four of the eight areas of sanitation as evidenced by the large number of sanitation deficiencies noted by our investigators during the inspection, and presented to you in the FDA 483, Inspectional Observations. The four areas of sanitation that were found deficient include the condition and cleanliness of food contact surfaces; prevention of cross-contamination; proper labeling and storage of toxic compounds; and exclusion of pests.

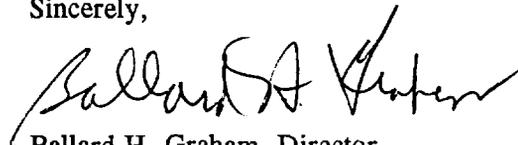
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,



Ballard H. Graham, Director  
Atlanta District